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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,545	02/12/2004	Kristian DiMatteo	10123/04501	5754

7590 07/23/2007

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EXAMINER	
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ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
07/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,545	DIMATTEO ET AL.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-28* is/are pending in the application.

4a) Of the above claim(s) *14,15,22 and 24-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-13,16-21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 16, and consequently all dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly submitted amendment to claims 1 and 16 pertaining to side walls being "on the same side as the inlet/first opening" is rather confusing to the examiner. First, it is rather unclear as to what "the same side" is intended to be, as catheters are tubular objects, with no clearly defined sides. Second, it would be the examiner's interpretation that being on the same side as an opening would mean that it is actually physically on the opening, as there is no clear reference to a definite side, other than the surface that the opening would cover. If that is the way it is to be interpreted, then it would seem that side walls on the same side of the opening would be walls on the opening itself, and would cover the opening and the opening would no longer be open. It seems as though there must be a clearer way of structurally defining the side walls.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Quinn (US Patent No. 6,461,321). Quinn discloses a distal tip for a catheter (Fig. 5) comprising: first (59a) and second (59b) lumens extending there through, wherein in an operative configuration, the first and second lumens are coupled to first (27a) and second (27b) lumens of a dual lumen catheter (24); a first opening (37) fluidly connected to the first lumen (59a) for inflow of fluid from a body lumen into which the distal tip is inserted in a normal mode of operation and for outflow of fluid thereto in a reverse mode of operation (col. 3, lines 7-11 and col. 7, lines 57-61); a second opening (89) fluidly connected to the second lumen (59b), the second opening being disposed distally from the first opening and separated therefrom by a selected stagger distance for outflow of the fluid therefrom when the catheter is in the normal mode of operation and for inflow of fluid from the body lumen in a reverse mode of operation (col. 3, lines 7-11 and col. 7, lines 57-61); a contoured flow deflection element (93) directing, in the reverse mode of operation, outflow from the first opening away from the second opening (col. 7, lines 57-61 state that if the flow is reversed such that blood flows out through the first opening then the inflow of blood through the second opening does not mix with the outflow of blood because the two are staggered apart, and the flow of blood out from the first opening (37) would inherently hit the ramped portion of the bolus (20) and be deflected upward and away from the second opening); a contoured outlet portion (78) of the second opening reducing an outflow velocity therefrom in the normal mode of

operation (col. 7, lines 53-56); and side walls extending between the first opening and the contoured flow deflection element (Fig. 5 discloses that the first opening actually opens at point (73), and Fig. 1 discloses that a side wall (labeled in Fig. 1 as either portion 37 or 98) that extends from the first opening (73) to the contoured flow deflection element (93). The portions of catheter walls that extend between these two points are walls that are found on the sides of the catheter. This is the examiner's interpretation as Applicant's claim language does not include any other structure of the side walls which would overcome the sidewalls disclosed by Quinn), the side walls being on the same side as the first opening (The examiner is unclear as to what Applicant means by "being on the same side as the first opening" as discussed in the 112 rejection above. Therefore, the examiner is taking the position that "being on the same side as the first opening" means that the side walls are on the same side of the catheter as the first opening. Since there are no defined sides to a tubular catheter, the examiner is taking the position that the "same side as the first opening" is the side of the catheter that the first opening is on, and this is best disclosed in Fig. 5, in which axis X divides the catheters into "sides", a side for the first opening (this side is anything that lies above the dotted line X in fig. 5) and the side for the second opening (this side is anything that lies below the dotted line X in fig. 5). Therefore any side walls that are found between the opening (37) and the contoured flow deflection element (93) will meet the limitations of the claim. As can be seen in Fig. 1 and 5, there are clearly walls on the sides of the catheter between these two points, and therefore Quinn discloses that there are side walls between the first opening and the contoured flow deflection element and the side

walls are on the same side as the first opening. Also, Fig. 5 further shows that line X passes midway between 26, and therefore half of 26 lies above line X. The portion of 26 that lies above line X, while small in dimension, still presents wall portions on the side of the catheter (side walls) and, as defined above, that are on the same side as the first opening. Applicant has not provided further structural limitations to the claim language that would distinguish over the side walls disclosed by Quinn).

In reference to claim 2, Quinn further discloses that the first and second openings are disposed on opposite sides of the distal tip (Fig. 5 and also see col. 3, lines 41-47) thereof.

In reference to claim 3, Quinn further discloses that the first and second openings have orifices (37 and 89) extending in planes angled with respect to a longitudinal axis (X) of the distal tip (as disclosed in Fig. 5).

In reference to claim 4, Quinn also discloses that the contoured flow deflection element (57) is adapted to direct outflow from the second opening (89) away from the first opening (37) in the normal mode of operation (Fig. 5 shows that the fluid flow would be directed along lumen 56 and would be then be directed outwards and downwards in the opposite direction from the first opening).

In reference to claim 5, Quinn also discloses that the distal tip is comprised of an atraumatic tip (col. 2, lines 65-66).

In reference to claim 6, Quinn further discloses that the first opening includes a first ramp portion (area nearest 20 in Fig. 5) that inherently deflects outflow therefrom

away from a longitudinal axis of the distal tip when in the reverse mode of operation (col. 7, lines 57-61).

In reference to claim 8, Quinn further discloses that the second opening (89) includes a second ramp portion (78) deflecting outflow from the second opening away form a longitudinal axis (X) of the distal tip in the normal mode (Fig. 5).

In reference to claim 9, Quinn also discloses that the second opening comprises an expanded section (Fig. 2, 71) increasing an exit plane cross sectional area of the second orifice (Fig. 5 also shows that the second orifice (89) expands upwards above the X-plane to create the expanded area).

In reference to claim 10, Quinn also discloses that the first and second lumens have D-shaped cross sections (Fig. 7).

In reference to claim 11, Quinn further discloses that the first ramp (near 20) is aligned with the first opening (37) and the second ramp (78) is aligned with the second opening (89) and there is an atraumatic distal tip (Fig. 2, 99).

In reference to claim 12, Quinn further discloses that the maximum radial dimension of the contoured bolus (99) is less than a radius of a catheter to which the distal tip is to be coupled (col. 6, lines 60-65).

Claims 16-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Quinn (US Patent No. 6,461,321). Quinn further discloses a flow control tip for a multi-lumen catheter comprising: an attachment portion (Fig. 5) adapted to fluidly connect to a distal portion of a catheter (24). Fig. 5 discloses that the flow control tip (93) attaches to

the distal end of the catheter (24) at the region disclosed as (34), also see col. 5, lines 49-51. Quinn further discloses a contoured bolus (93) defining at least a portion of an inlet (37) and an outlet (89) of the distal tip so that, when coupled to a catheter, the inlet is coupled to a first one of the catheter lumens (59a) and the outlet is coupled to a second one of the catheter lumens (59b), and a flow deflector (78) directing fluids exiting the inlet in a first mode away from the outlet and side walls (The examiner is unclear as to what Applicant means by "being on the same side as the first opening" as discussed in the 112 rejection above. Therefore, the examiner is taking the position that "being on the same side as the first opening" means that the side walls are on the same side of the catheter as the first opening. Since there are no defined sides to a tubular catheter, the examiner is taking the position that the "same side as the first opening" is the side of the catheter that the first opening is on, and this is best disclosed in Fig. 5, in which axis X divides the catheters into "sides", a side for the first opening (this side is anything that lies above the dotted line X in fig. 5) and the side for the second opening (this side is anything that lies below the dotted line X in fig. 5). Therefore any side walls that are found between the opening (37) and the contoured flow deflection element (93) will meet the limitations of the claim. As can be seen in Fig. 1 and 5, there are clearly walls on the sides of the catheter between these two points, and therefore Quinn discloses that there are side walls between the first opening and the contoured flow deflection element and the side walls are on the same side as the first opening. Also, Fig. 5 further shows that line X passes midway between 26, and therefore half of 26 lies above line X. The portion of 26 that lies above line X, while small in dimension, still

present wall portions on the side of the catheter (side walls) and, as defined above, that are on the same side as the first opening. Applicant has not provided further structural limitations to the claim language that would distinguish over the side walls disclosed by Quinn) extending between the inlet and the bolus (Fig. 5 discloses that the first opening actually opens at point (73), and Fig. 1 discloses that a side wall (labeled in Fig. 1 as either portion 37 or 98) that extends from the first opening (73) to the contoured flow deflection element (93). The portions of catheter walls that extend between these two points are walls that are found on the sides of the catheter. This is the examiner's interpretation as Applicant's claim language does not include any other structure of the side walls which would overcome the sidewalls disclosed by Quinn) wherein the contoured bolus defines a specified stagger distance between the inlet and the outlet (Fig. 1).

In reference to claim 17, Quinn also discloses that the contoured bolus further comprises a second flow deflector (near 20) directing fluid exiting the outlet in a second mode away from the inlet (col. 7, lines 57-61).

In reference to claim 18, Quinn also discloses that the inlet and the outlet are formed on opposite surfaces of the contoured bolus (Fig. 5, also see col. 3, lines 41-47).

In reference to claim 19, Quinn further discloses that the flow deflector comprises a ramp (near 20) disposed adjacent an inlet opening (37).

In reference to claim 20, Quinn also discloses that the contoured bolus defines an expanded section (Fig. 5 discloses that directly above element 91, the lumen 56

expands upwards so that it expands above the x-axis) which increases an exit plane cross-sectional area of the outlet.

In reference to claim 21, Quinn further discloses that the size of the expanded section is selected to reduce an exit pressure (col. 7, lines 51-57).

In reference to claim 23, Quinn also discloses that the attachment portion is adapted for attachment to the catheter by thermal bonding (col. 5, lines 51-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US Patent No. 6,461,321) in view of Dasse et al. (US Patent No. 5,171,216). Quinn discloses the device substantially as claimed, however, Quinn does not disclose expressly that the stagger distance between the openings is between 1 and 1.5 cm. Dasse, however, discloses a distal tip of a catheter with a stagger distance between the openings (Fig. 3, 14 and 16) that can be anywhere in the range of 1-4 cm (see col. 5, lines 7-13). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quinn with the stagger distance as specified by Dasse in order to provide an optimal distance between the openings such that mixing

of the blood does not occur, yet also to ensure that the distal tip of the catheter can still be maneuverable within a vascular system.

Response to Arguments

Applicant's arguments filed 5/10/2007 have been fully considered but they are not persuasive. As discussed above, it is unclear what structure "the same side" imparts to the claim language. Also discussed above, it is the examiner's position that anything above the line X in Fig. 5 is considered to be on the same side as the first opening/inlet, and therefore there are side walls extending between the first opening and the contoured flow deflection element as shown in Figs. 1 and 5. Furthermore, while Applicant has argued that side walls are meant to extend and curve upwards around the opening to prevent radially spilling, these structural limitations have not been added to the claims. Also discussed above, Applicant's arguments that Fig. 8 shows a flat septum and no side walls, is countered with the examiner's position that Fig. 5 shows anything above line X to be on the same side as the first opening. Fig. 5 further shows that line X passes midway between 26, and therefore half of 26 lies above line X. The portion of 26 that lies above line X, while small in dimension, still present wall portions on the side of the catheter (side walls) and, as defined above, are on the same side as the first opening.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons